Every surgeon who routinely perform beating-heart bypass should be conscious about these results, make the patients aware, and discuss with them the opportunity to perform beating-heart bypass.

Sometimes, journals with a low impact factor tend to publish works with less reliable conclusions.[6]

Karl Popper, one of the most influential philosophers of science of the 20th century, said: "If we are uncritical we shall always find what we want: we shall look for, and find, confirmations, and we shall look away from, and not see, whatever might be dangerous to our pet theories."[7]

Umberto Benedetto, MD
Giovanni Melina, MD
Emiliano Angeloni, MD
Riccardo Sinatra, MD
University of Rome Sapienza
II Faculty of Medicine
Department of Cardiac Surgery
Rome, Italy

References

1. Benedetto U, Angeloni E, Sinatra R. Reply to the Editor. *J Thorac Cardiovasc Surg*. 2010;139:1670-1.
2. Wijeysundera DN, Beattie WS, Djaiani G, Rao V, Borger MA, Karkouti K, et al. Off-pump coronary artery surgery for reducing mortality and morbidity: meta-analysis of randomized and observational studies. *J Am Coll Cardiol*. 2005;46:872-82.
3. Shroyer AL, Grover FL, Hattler B, Collins JF, McDonald GO, Kozora E, et al, for the Veterans Affairs Randomized On/Off Bypass (ROOBY) Study Group. On-pump versus off-pump coronary-artery bypass surgery. *N Engl J Med*. 2009;361:1827-37.
4. Møller CH, Perko MJ, Lund JT, Andersen LW, Kelbaek H, Madsen JK, et al. No major differences in 30-day outcomes in high-risk patients randomized to off-pump versus on-pump coronary bypass surgery: the best bypass surgery trial. *Circulation*. 2010;121:498-504.
5. Sousa Uva M, Cavaco S, Oliveira AG, Matias F, Silva C, Mesquita A, et al. Early graft patency after off-pump and on-pump coronary bypass surgery: a prospective randomized study. *Eur Heart J*. 2010;31:2492-9.
6. Raja SG, Berg GA. Outcomes of off-pump coronary artery bypass surgery: current best available evidence. *Indian Heart J*. 2007;59:15-27.
7. Popper KR. The unity of method [chapter 29]. In: *The poverty of historicism.* Boston, Mass: Beacon Press; 1957.

doi:10.1016/j.jtcvs.2011.06.004

ENDOSCOPIC VERSUS OPEN SAPHENOUS VEIN HARVEST TECHNIQUE IN THE RANDOMIZED ON/OFF BYPASS (ROOBY) TRIAL

To the Editor:

We read with interest the article by Zenati and colleagues[1] describing the results of endoscopic versus open saphenous vein harvest technique on coronary artery bypass grafting (CABG) outcomes.[1] The authors performed a subgroup analysis of the Randomized On/Off Bypass (ROOBY) trial, designed to evaluate differences in clinical outcomes between patients undergoing on- and off-pump CABG.[2] Of the 2203 patients recruited into the original trial, 1471 (66.8%) had conduit data recorded and 894 (40.6%) had angiographic follow-up at 1 year. These latter 2 groups formed the basis of the subgroup analysis, in which the authors found inferior rates of saphenous vein graft patency and increased repeat revascularization rates in the endoscopic vein harvest (EVH) group.

This interesting article has some limitations that should be considered.

1. Learning curve. The study began in 2002, when EVH uptake in the United States was low (<10%). The variability in experience levels, the effect of the learning curve, and the potentially low number of cases per institution or practitioner should be considered when interpreting these findings.
2. Technical details. Data regarding technical details during conduit harvest and intraoperative flow characteristics were unfortunately not recorded during this study and may have an effect on graft patency.
3. Selection bias. The primary purpose of the study was not to compare vein harvest techniques. Surgeons were encouraged to use whichever harvesting technique they preferred, and a selection bias may exist with unmeasured confounders affecting surgeons' decision to use an EVH approach.
4. Repeat revascularization rates. The authors provide minimal insight into the potential reasons for the observed increased revascularization rates in the EVH group. It is interesting to note that in the whole population studied (n = 1414), there was no difference in revascularization rates between the EVH and open vein harvest groups (5.2% vs 3.5%, $P = .13$). Were the revascularizations symptom-driven or simply the result of an "occulo-stenotic reflex"? If the latter is true, then indeed the clinical relevance of the finding of increased saphenous vein graft occlusion in the EVH group is unclear. Furthermore, recent evidence from a large observational trial using both multivariable- and propensity-adjusted analyses actually shows a survival advantage and no increase in revascularization rates with the EVH technique.[5]
5. Literature review. Finally, at least 2 important articles examining the long-term clinical impact of EVH were omitted in the discussion. Our group recently published a large observational study showing no association between EVH and midterm freedom from death or readmission to hospital for cardiac catheterization, repeat revascularization, acute coronary syndromes, or heart failure.[3] Allen and colleagues[4] found no difference in 5-year outcomes in a small but randomized study.

We do strongly agree with the authors' conclusions that the time has come for a large prospective, randomized study examining both angiographic and clinical outcomes in patients undergoing CABG with open or endoscopic saphenous vein harvesting. It will be important for such a trial to have strict protocols regarding EVH technique and the experience of the vein harvester, and some

assessment of intraoperative graft quality and patency.

Maral Ouzounian, MD
Imtiaz S. Ali, MD, FRCSC
Division of Cardiac Surgery
Dalhousie University
Halifax, Nova Scotia, Canada

References

1. Zenati MA, Shroyer AL, Collins JF, Hattler B, Ota T, Almassi GH, et al. Impact of endoscopic versus open saphenous vein harvest technique on late coronary artery bypass grafting patient outcomes in the ROOBY (Randomized On/Off Bypass) Trial. *J Thorac Cardiovasc Surg*. 2011;141:338-44.
2. Shroyer AL, Grover FL, Hattler B, Collins JF, McDonald GO, Kozora E, et al. On-pump versus off-pump coronary-artery bypass surgery. *N Engl J Med*. 2009;361:1827-37.
3. Ouzounian M, Hassan A, Buth KJ, MacPherson C, Ali IM, Hirsch GM, et al. Impact of endoscopic versus open saphenous vein harvest techniques on outcomes after coronary artery bypass grafting. *Ann Thorac Surg*. 2010;89:403-9.
4. Allen KB, Heimansohn DA, Robison RJ, Schier JJ, Griffith GL, Fitzgerald EB. Influence of endoscopic versus traditional saphenectomy on event-free survival: five-year follow-up of a prospective randomized trial. *Heart Surg Forum*. 2003;6:E143-5.
5. Dacey LJ, Braxton JH, Kramer RS, Schmoker JD, Charlesworth DC, Helm RE, et al. Long-term outcomes of endoscopic vein harvesting after coronary artery bypass grafting. *Circulation*. 2011;123:147-53.

doi:10.1016/j.jtcvs.2011.05.027

Reply to the Editor:

We thank Ouzounian and Ali for their comments. As discussed in the ''Materials and Methods'' section of our article,[1] they correctly point out that the Veterans Affairs Cooperative Studies Program 517 Randomized On/Off BYpass (ROOBY) trial[2] was initiated in 2002 with the endoscopic vein harvest (EVH) preplanned subanalysis initiated later (in 2003, with some centers obtaining institutional review board approval in 2004). For the period of enrollment that applies to our EVH subanalysis (late 2003–2008), the penetration of EVH in coronary artery bypass grafting in the United States and the Veterans Health Administration was approximately 70%, well past the learning curve (M.A.Z., unpublished data, February 2011). Although the of Ex-Vivo Vein Graft Engineering via Transfection (PREVENT) IV Trial subanalysis[3] was criticized precisely for the reason raised by Ouzounian and Ali, our subanalysis was conducted after the EVH learning curve was mastered.

In the ROOBY trial, repeat revascularization was primarily ischemia-driven. However, some asymptomatic ROOBY patients may have underwent repeat revascularization at the time of protocol-mandated angiography based on severe native coronary artery stenosis in the presence of occluded saphenous vein graft.

Given the main ROOBY trial's focus was to compare off-pump versus on-pump coronary artery bypass grafting outcomes, EVH-related technical details and harvester's experience were not gathered. A new prospective randomized trial funded by the Veterans Affairs Central Office has been proposed by our team and has received initial funding for expanded project planning (Cooperative Studies Program 588 REGROUP).

The ROOBY trial co-authors concur that it is possible that selection bias may have played a role in the subanalysis performed. The REGROUP team plans to use randomization, to capture surgical technical details, and to evaluate more rigorously the role of harvester's experience on outcomes.

The ROOBY trial team concurs with the stated need for a large, multicenter prospective randomized trial to definitively address the issue of safety and efficacy of EVH. Pending Veterans Affairs Central Office Cooperative Studies Program approval and funding, the REGROUP trial will rigorously address these outstanding questions comparing saphenous vein graft harvest approaches appropriately.

Marco A. Zenati, MD[a]
A. Laurie Shroyer, PhD, MSHA[b]
[a]*Veterans Affairs*
Boston Healthcare System
and Harvard Medical School
Boston, Mass
[b]*Veterans Affairs*
Northport Medical Center
and Stony Brook University Medical School
Northport, NY

References

1. Zenati MA, Shroyer AL, Collins JF, Hattler B, Ota T, Almassi GH, et al. Impact of endoscopic versus open saphenous vein harvest technique on late coronary artery bypass grafting patient outcomes in the ROOBY (Randomized On/Off Bypass) Trial. *J Thorac Cardiovasc Surg*. 2011;141:338-44.
2. Shroyer AL, Grover FL, Hattler B, Colling JF, McDonald GO, Kozora E, et al. On-pump versus off-pump coronary artery bypass surgery. *N Engl J Med*. 2009;361:1827-37.
3. Lopes RD, Hafley GE, Allen KB, Ferguson TB, Peterson ED, Harrington RA, et al. Endoscopic versus open vein graft harvesting in coronary artery bypass surgery. *N Engl J Med*. 2009;361:235-44.

doi:10.1016/j.jtcvs.2011.06.008